AGENDA

CIRCULATORY SYSTEM DEVICES PANEL

June 19, 2000 Gaithersburg Hilton 620 Perry Parkway, Gaithersburg, Maryland

10:00 a.m.

Call to Order

Anne B. Curtis, M.D.

Chairperson

Conflict of Interest Statement

Megan Moynahan Executive Secretary

10:15 a.m.

Open Public Hearing*

10:45 a.m.

Cordis Corporation

PMA P990036

Cordis Checkmate™ System

Dennis Donohoe, M.D.

Cordis Corporation

David R. Holmes, M.D.

Mayo Clinic Rochester, MN

Richard E. Kuntz, M.D., M.Sc.

Cardiovascular Data Analysis Center

Boston, MA

11:45 a.m.

FDA Presentation

John E. Stuhlmuller, M.D.

Lead and clinical reviewer

12:15 p.m.

Lunch

1:15 p.m.

Open Committee Discussion

Anne B. Curtis, M.D. Chairperson

3:00 - 3:15 p.m.

Break

Open Public Hearing**

6:00 p.m.

Adjourn

10:15 - 10:45 a.m. OPEN PUBLIC HEARING*

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

Ms. Moynahan will present the speakers who have requested time for presentation to the Panel. After the scheduled speakers have spoken, the Chair may ask them to remain if the committee wishes to question them further. Dr. Curtis will recognize unscheduled speakers as time allows.

Note: Only the Chair and members of the Panel may question speakers during the open public hearing.

Scheduled Speakers are given a ten-minute limit.

Name

Affiliation

Unscheduled speakers may have time designated by the Chair.

OPEN PUBLIC HEARING**

Near the end of the committee deliberations, on each specific device being discussed, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee.